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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/796,782	03/09/2004	George J. Brewer	4100.001099	1675

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EXAMINER	
MAIER, LEIGH C	

ART UNIT	PAPER NUMBER
1623	

DATE MAILED: 12/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/796,782	BREWER ET AL.	
	Examiner	Art Unit	
	Leigh C. Maier	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 10/3/05.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *40 and 80-122* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *40 and 80-122* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

Claims 44 and 90-115 are again rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, as set forth in the previous Office action. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that Applicant, at the time the application was filed, had possession of the claimed invention.

Applicant's arguments filed October 3, 2005 have been fully considered but they are not persuasive.

Applicant objects to the citation of *UC v. Lilly* and states that this case is not on point because "in Lilly a genus of previously unknown compounds was being claimed, while here, use of known compounds is being claimed." However, this does not appear to be consistent with Applicant's footnote stating "... compounds identified or produced at some future date which possess the required functional capacity will also fall within the scope of the claims."

Applicant further cites *Capon v. Eshhar* and appears to draw a parallel between *Capon* and the instant case. In *Capon*, the court finds that both parties have adequate written description and states "[b]oth parties point of their specific examples of chimeric DNA prepared using *identified known procedures*, along with citation to the scientific literature as to every step of the

preparative method." (emphasis added) See page 1082. The instant specification presents no such method of preparing/identifying compounds that would meet the functional limitations of the claims. Other than thiomolybdate derivatives, one of ordinary skill would be left selecting compounds at random for screening. The examiner maintains that in the instant case, the art has not evolved to the point obviating the need for more description of the agent—other than thiomolybdates—that are contemplated. As noted previously, a description in terms of function may be adequate when the functional characteristics are coupled with a known or disclosed with a known correlation between function and structure or by a combination of such identifying characteristics, sufficient to demonstrate that Applicant was in possession of the claimed genus.

Applicant contends that the facts of the instant case are wholly different from those of *Rochester* because the specification in that case did not disclose any compounds whereas the instant specification does disclose compounds. The examiner agrees that the specification does describe thiomolybdates. However, Rochester was cited regarding the "compounds identified or produced at some future date which possess the required functional capacity [that] will also fall within the scope of the claims." These compounds are not described by other than functional language. Neither is there any systematic process described whereby one of ordinary skill might identify/produce them.

Finally, Applicant argues that the number of disclosed compounds, citing particular passages in the specification, is believed to be more than representative and thereby satisfy the written description requirement. The examiner maintains that these disclosed compounds are representative of a genus of "thiomolybdate derivatives having the ability to form a complex with copper and a protein" but not the genus recited in the claims.

Claims 44 and 80-115 are again rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement, as set forth in the previous Office action. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant's arguments filed October 3, 2005 have been fully considered but they are not persuasive.

Applicant contends that the claims are not directed to making agents useful for the recited methods of treatment, so whether or not the specification teaches how to make agents other than thiomolybdate derivatives is irrelevant. The examiner disagrees. In order to practice the recited method commensurate with the scope of the claims, one of ordinary skill must make or otherwise obtain the agents necessary to do so. Therefore, the examiner was reiterating that the claims were not enabled for the "compounds identified or produced at some future date." The specification is enabling for the preparation of thiomolybdate derivatives. Applicant notes that the specification teaches the use of other copper-chelating agents. However, the claims are not drawn to copper-chelating agents, per se, but specifically to those that form a complex with copper and protein.

Applicant contends that angiogenesis requires copper, and the specification demonstrates that the recited method reduces free copper. "Thus, one of ordinary skill in the art at the time the application was filed would have predicted that a method that would reduce free copper would have a detrimental effect on any and all biological processes which require free copper, such as angiogenesis." The examiner maintains that one of ordinary skill would probably find that the

use of the recited agents would have a credible utility but not necessarily that the method, as described, was fully enabled.

Applicant objects to the use of the cited references because details of the experiments are not provided. However, the references must be considered at face value, and while the examiner finds the utility to be credible in theory, the references cast doubt on whether the specification is adequately enabling for the methods. The references therefore shift the burden back to Applicant to provide sufficient evidence that the methods are in fact enabled. Moreover, while the references do not provide all the experimental details and data for the examiner to consider, Applicant presumably *is* in possession of such data and details. Furthermore, it is expected that if it is Applicants position that the methods are fully enabled, Applicants would be in a position to submit evidence rebutting these negative reports. The examiner finds no such submission.

Applicant further states that "[i]t is simply improbably [sic] that reducing free copper would have absolutely no effect on a biological process which requires free copper." While there may be an "effect," if there is no measurable benefit, it is not clear that such a method qualifies as "treatment." It may be that for some of these diseases, that more than one factor, such as copper reduction, is critical to (beneficial) treatment.

It appears to be Applicant's position that the examiner should have made a rejection based on utility and traverses this hypothetical rejection by citing MPEP 2107.01, which states that there is no requirement that a therapeutic method be fully effective. Applicant further states that "[w]hether the method is safe or economically practicable is not relevant to patentability." This is noted. However, there was no lack of utility alleged.

Claims 116-122 are again rejected under 35 U.S.C. 112, first paragraph, because the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims, as set forth in the previous Office action. The claims appear to be enabled for the treatment of vascularization associated with cancer but not the other recited diseases.

Applicant's arguments filed October 3, 2005 have been fully considered but they are not persuasive.

Applicant asserts that because of the positive results seen in the treatment of cancer, "[one] of ordinary skill would be even more likely to predict a similar result in treating other conditions." The examiner maintains that one of ordinary skill would reasonably expect that such a method has credible utility, but the negative results seen in references discussed above cast doubt on the enablement commensurate with the scope of the claims, shifting the burden onto Applicant to demonstrate enablement.

Claim Rejections - 35 USC §§ 102 and 103

Claims 116, 117, and 120 are again rejected under 35 U.S.C. 102(a) as being anticipated by Merajver, et al (Proc. Angiogen. Cancer, 1998), as set forth in the previous Office action.

Claim 119 is again rejected under 35 U.S.C. 103(a) as being unpatentable over Merajver, et al (Proc. Angiogen. Cancer, 1998), as applied to claims 116, 117, and 120 above, as set forth in the previous Office action.

Applicant states that a copy of the *Katz* declaration submitted in the parent application obviates these rejections. However, the examiner does not find the copy of this declaration present in Applicant's submission.

Double Patenting

Claims 44, 80, 83-85, 104, 106, 107, and 116-122 are again rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 43-48 and 57 of U.S. Patent No. 6,703,050, as set forth in the previous Office action.

Claims 116, 117, 119, and 122 are again rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 3, 15-18, and 36-42 of U.S. Patent No. 6,703,050.

Applicant has previously indicated a willingness to file a terminal disclaimer if necessary upon a finding of allowable subject matter.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Examiner's hours, phone & fax numbers

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh Maier whose telephone number is (571) 272-0656. The examiner can normally be reached on Tuesday, Thursday, and Friday 7:00 to 3:30 (ET).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Anna Jiang (571) 272-0627, may be contacted. The fax number for Group 1600, Art Unit 1623 is (571) 273-8300.

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Leigh C. Maier

Leigh C. Maier
Primary Examiner
December 6, 2005